



CARSON PRODUCTS COMPANY

P O BOX 22309 SAVANNAH, GEORGIA 31403 (912) 232-8114

1982 NOV -2 AM 10: 50

November 1, 1982

Dockets Management Branch  
(HFA-305)  
Food & Drug Administration  
Room 4-62  
5600 Fisher's Lane  
Rockville, Maryland 20857

RE: Skin-Bleaching Drug Products  
for Over-the-Counter Human Use;  
Tentative Final Monograph Docket No. 78N-0065

Dear Sir or Madam:

Carson Products Company submits these comments in response to the Agency's publication of a Tentative File Monograph that would establish conditions under which the over-the-counter skin bleaching drug products are generally recognized as safe and not misbranded. 47 Fed. Reg. 39108 (Sept. 3, 1982). Carson Products Company is a manufacturer of cosmetic products primarily for use by Blacks and other darker-skinned ethnic groups. Because Carson Products Company produces a skin-bleaching product which would be affected by the proposed regulations, it is taking this opportunity to present the viewpoint of a manufacturer of ethnic products.

The Tentative Final Monograph in paragraphs 7 and 8 addresses the issue of labeling so that the product will not be misbranded. The Agency has concluded that the terms "skin-bleaching" and "skin-lightener" may be used. The term "tone" may not be used. This will be particularly unfair to Carson Products Company since the actual trade name of its product is "Doctor Fred Palmer Ultra Bleach and Tone Cream." This is a trade name which Carson Products Company has protected and in which it has a proprietary interest. The name is not a new one. It came into existence in the late 1960's. Carson Products Company's skin-bleaching product has been actively sold under this name since November, 1970. There is a very substantial product identification with this name in the Black community.

78N-0065

MAGIC SHAVING PRODUCTS / DARK & LOVELY PRODUCTS / GODEFROY HAIR COLOR / DR. FRED PALMER PRODUCTS

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Since bringing this product onto the market, Carson Products Company has had two marketing studies prepared for it relating to skin-bleaching products. The first was prepared by Oxtoby-Smith, Inc. in January, 1973. This study is entitled "An Exploratory Study of the Beauty Care Needs of Black Women." The study was prepared by holding six focused group sessions with Black women during late November and early December, 1972. The women interviewed were in the age bracket of eighteen to fifty years of age. There were sessions held in Birmingham, Alabama, Los Angeles, California, St. Louis, Missouri, and New York, New York. From these sessions, Oxtoby-Smith, Inc. concluded:

"A frequent complaint among Black women, particularly about their facial skin, is the presence of uneven skin tones and dark spots or pits left by blemishes."

The women interviewed recognize the purpose of a toner/bleach product and openly discussed the needs for such a product in their beauty care programs.

The second study was done by Oxtoby-Smith, Inc. in April, 1974, and was entitled "Black Women's Usage of and Attitudes Toward Selected Hair and Skin Care Products." This study was based on personal interviews with 250 Black women. These interviews were taken across the United States. Of the women interviewed, twenty-four percent reported that they were currently using a "skin-toning product." Another fourteen percent responded that they had used a "skin-toning product" in the past but had since discontinued use mainly because of dissatisfaction with available products. In discussing these products, these Black women stated that the problem they were hoping to solve was "uneven skin tones, spots which are darker than the rest of the facial skin or spots which are lighter than the rest of the facial skin, or both lighter and darker spots." The most appealing aspect of Carson Products Company's "Doctor Fred Palmer's Ultra Bleach and Tone Cream" to the Black women interviewed was the concept that it would even out the facial skin tones by bleaching darker spots.

It is clear from these market studies that Black women in the early to middle seventies recognized that skin-toner/bleaching

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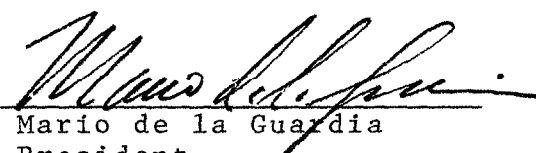
products were intended to bleach out darker areas of skin thereby giving the skin a more even color tone. As a follow-up, Carson Products Company has recently interviewed a number of its Black distributors and customers. Responses from some of these individuals are attached to this comment. These letters confirm that the members of the Black community on a nation-wide basis still recognize the purpose of a skin-toner/bleaching product. None of those interviewed by Carson Products Company thought that its "Doctor Fred Palmer Ultra Bleach and Tone Cream" was intended to affect the "healthy elasticity" of the skin.

The trade name "Doctor Fred Palmer's Ultra Bleach and Tone Cream" has a strong recognition in the Black community. This trade name is a proprietary right of Carson Products Company and valuable to it. Moreover, the use of this trade name has not resulted in any misconceptions as to the product's use amongst Blacks. For at least the last eight years, Blacks have recognized that the product's intended use is to bleach dark spots thereby giving the color of the skin a more even appearance. On the contrary, to require the deletion of the word "tone" from the trade name would be misleading in that it would imply that the product was a bleaching agent for overall use as opposed to a product which was intended for localized use to help even out skin color tones.

For the reasons stated above, Carson Products Company disputes the Agency's findings contained in paragraphs 7 and 8 of the Tentative Final Monograph and requests that those portions of the proposed regulation relating to the deletion of the word "tone" from the indications be revised.

Sincerely,

CARSON PRODUCTS COMPANY

By:   
Mario de la Guardia  
President

MG/ms  
Enclosure



PAUL'S SUNDRIES, INC. 8543 LANKERSHIM BLVD. □ SUN VALLEY, CALIF. 91352

PHONE 875-1195 □ 767-6915

October 28, 1982

Carson Products Company  
P. O. Box 22309  
Savannah, Georgia 31403

Dear Sir,

After being in the ethnic product distribution for 15 years, and handling Dr. Palmers all those years, it seems strange that someone would question how Dr. Palmers Ultra Bleach 'N' Tone is used. Being one of the largest users of ethnic hair and skin products in the country and taking care of countless requests, many customers and accounts, we are well aware of how and why products are bought. Dr. Palmers is not used for the improvement of elasticity of the skin, tightening of the skin, or taking care of wrinkles in the skin. In fact we have yet had a call for such products from our accounts! Dr. Palmers is used the same way as Nadinola, Artra, or Ultra Bleach 'N' Glow. Those products, as well as Dr. Palmers, are used for evening skin tones and blotches. In addition Dr. Palmers is used to lighten dark areas and to fade dark spots on the skin. I hope this clears up any misunderstanding concerning Dr. Palmers use.

Sincerely,

Jerry Davis  
President

JD/bc



# STANDARD DRUG SUPPLY CO.

WHOLESALE DRUGS

• COSMETICS

• SUNDRIES

13955 JOS CAMPAU

DETROIT, MICHIGAN 48212

PHONE 366-7000

October 26, 1982

Carson Products Company  
P.O. Box 22309  
Savannah, Georgia 31403

Attn: John Brown

Dear John,

The word "tone" derives from the Latin "tonus" or tension, and from the Greek "tonos" or act of stretching. The first six of Webster's definitions refer to "tone" in regards to sound, and the manners of speaking and writing. The seventh definition refers to "color quality or value" and "a tint or shade of color".\* The seventh definition applies to the commonly accepted use of the word "tone" as it applies to skin care products containing hydroquinone.

Standard Drug Supply has specialized in Black health and beauty aids for 35 years, we have sold Dr. Fred Palmer Ultra Bleach & Tone Cream for over 10 years. Our customers know that the word "tone" refers to color and that "skin tone creams" are not "skin toning creams". We have never had a conceptual, or marketing problem with this category of merchandise. Please note that we average \$25,000 a month in sales in the skin tone category.

Sincerely,

Daniel Medow

DM/bym

\* Webster's Seventh New Collegiate Dictionary  
Copyright 1967 Pg 931



## Ben Sheftall Distributing Company, Inc.

October 28, 1982

Mr. John E. Brown III  
Sales Promotion Manager  
Carson Products Company  
P. O. Box 22309  
Savannah, GA 31403

Dear John:

As per our conversation, I would like to address the questions and concerns in relationship to the FDA and their investigation into the Dr. Fred Palmer products.

A little background about our products. We have been selling, servicing, and specializing in ethnic health and beauty aids for approximately 40 years. We have carried the Dr. Fred Palmer line for many of those 40 years. As you and I discussed, I must add that I consider Ultra Bleach and Tone, Dr. Fred Palmer, Ambi, Artra, Nadinola, Ultra Glow, etc. as products that are used by black consumers to even out the skin tone, and to fade out dark spots and blotches. In no way, shape or form have I ever thought that we are selling these products to remove wrinkles. Certainly, I was not aware of any claims that you have made, nor any advertising that leads to this belief.

I feel also, that I can comfortably say that most, if not all of our consumers believe just what I have outlined in the above paragraph.

If I can be of any further assistance to you, or your company, please contact me. Once again, I thank you for your cooperation and consideration in each and every one of our endeavours.

Sincerely,

Richard M. Eichholz  
President

RME:lwH